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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FRANK, RODNEY T	

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/054,487	LAUMAN ET AL.
	Examiner	Art Unit
	Rodney T. Frank	2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 5, 7, 8, 12, 14, 15-17, 20, 28-34, 36, 40, 41, 43-45, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (U.S. Patent Number 5,135,485; hereinafter referred to as Cohen). Cohen discloses a capacitance-type fluid level sensing system, method, and device is disclosed for determining the amount of fluid in a container, for example, a disposable plastic bag used for intravenous (i.v.) injection or collection of waste from a human body (catheter). In one illustrated embodiment, conductive plates are disposed on the outside of the plastic bag and connected to a circuit for detecting any change in the capacitance of

the capacitor formed thereby. In another embodiment, the conductive plates are integrally constructed as part of a surface of the electronic device housing, such that the fluid level can be detected when the housing is affixed directly to the outside of the bag. Alternative annunciation, detection, flow rate calculation, display, and housing features are shown in various embodiments (please see the abstract).

3. With regard to claims 1 and 12, Cohen disclose and shows in the figures with particular, a device for providing a medical fluid or dialysis to a patient comprising a plurality of capacitor plates (10 and 12) positioned to define a space between plates (see specifically the embodiment shown in figures 13-14a); a fluid receptacle positioned between the capacitor plates (13 in figure 1, 102 in figure 13), a circuit electrically connected to the capacitor plates having an output indicative of a volume of the fluid in the receptacle (see 15 in figure 1 and column 5 lines 3-13) a member (not shown) for providing at least a portion of the volume of the fluid to or from a patient.

In reference to claim 5, the plastic i.v. or catheter bag would comprise first and second membrane walls moveable to change a volume of the receptacle.

In reference to claims 7 and 8, in column 4 beginning with line 53 through column 5 line 2, Cohen discloses various embodiments of the capacitors whereby the capacitor plates can take on various shapes, one of which would be the actual shape of the container. Therefore a plate with a non-planar shape and a plate, which is substantially the same shape as the container either full or empty, are disclosed.

In reference to claim 11, the capacitor plates are shown to be substantially parallel (see figure 11, for example).

In reference to claim 14, a system for measuring a volume of fluid provided to or from a patient, the fluid receptacle capable of being fluidly connected to a patient, first and second capacitor plates having a variable dielectric between the plates that is dependent on an amount of a fluid in the fluid receptacle, and a circuit connected to the capacitor plates that creates a signal related to the variable dielectric is disclosed in view of the Cohen reference.

In reference to claims 15-17, the method of measure disclosed in Cohen would meet these claim limitations.

In reference to claim 20, the fluid receptacle positioned between the capacitor plates is shown in figure 13.

In reference to claims 28 and 29, it is disclosed conventional circuitry can be used to determine capacitance. Since a processor would be a part of conventional capacitive measurement circuitry, then this limitation is disclosed and further a processor that determines a cumulative volume would therefore be disclosed in the scope of the processor as well.

In reference to claim 30, the shape of the plates was already covered in view of the discussion of claim 8 above.

In reference to claims 31-34, 36, 40, 41, 43-45, and 47, these claims were discussed at great details in reference to the previous claims discussed in the

paragraphs above and these claims are therefore deemed to be disclosed in view of the Cohen reference.

4. Claims 1, 2, 7, 8, 11-17, 20, 30-33, 36, 40, 43-45, 47, and 51-56 rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (U.S. Patent Number 6,562,012; hereinafter referred to as Brown). Brown discloses a capacitive-based apparatus for measuring the volume of a fluid drop passing through an intravenous drip chamber. The apparatus includes a capacitor comprising two parallel plates that are a fixed distance apart and are positioned such that the fluid flow path in the drip chamber is between them. The fluid drop moving through the drip chamber between the plates causes the capacitance of the plates to change. This change in capacitance is measured and from it, the volume of the drop is calculated. The volumes of a series of drops are integrated to provide a measured rate of flow through the drip chamber. This measured rate of flow is compared to the programmed rate of flow and the difference is used to adjust a flow control device to obtain the desired rate of flow. The measured flow rate is also displayed (Please see the abstract).

5. With regard to claims 1,12, and 13, Brown discloses, with reference to figure 1, a device for providing a medical fluid or dialysis to a patient comprising a plurality of capacitor plates (42) positioned to define a space between plates; a fluid receptacle positioned between the capacitor plates (12), a circuit electrically connected to the capacitor plates having an output indicative of a volume of the fluid in the receptacle

(see column 5 line 34 through column 6 line 22) a member (40) for providing at least a portion of the volume of the fluid to or from a patient.

With regard to claim 2, Brown discloses the use of the receptacle (12) operating with a pump chamber (20).

In reference to claims 7 and 8, in column 4 beginning with line 53 through column 5 line 2, Cohen discloses various embodiments of the capacitors whereby the capacitor plates can take on various shapes, one of which would be the actual shape of the container. Therefore a plate with a non-planar shape and a plate, which is substantially the same shape as the container either full or empty, are disclosed.

With reference to claim 11, the capacitor plates are shown to be substantially parallel in each of the figures.

In reference to claims 15-17, the method of measure disclosed in Brown would meet these claim limitations.

In reference to claim 20, the fluid receptacle positioned between the capacitor plates is shown in figure 1.

In reference to claim 30, in column 5 beginning with line 5 through line 11, Cohen discloses various embodiments of the capacitors whereby the capacitor plates can take on various shapes, one of which would be the actual shape of the container. Therefore a plate with a non-planar shape and a plate, which is substantially the same shape as the container either full or empty, are disclosed.

In reference to claims 31-33, 36, 40, 43-45, 47, and 51-56, these claims were discussed at great details in reference to the previous claims discussed in the

paragraphs above and these claims are therefore deemed to be disclosed in view of the Brown reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-4, 6, 9, 10, 11, 13, 18, 19, 21-27, 35, 37-39, 42, 46, 48-50, and 51-73 rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al.

7. In reference to claim 2, since the Cohen reference is used with an i.v. bag, which is known to be utilized with a pump chamber to deliver the fluid contained therein, though this limitations is not specifically disclosed, this limitation is deemed as obvious to one of ordinary skill in the art since this is within the realm of general operation of an i.v. system.

In reference to claim 3, the capacitor plates are shown to have a shape similar to that of the chamber (see specifically figure 1 item 34).

In reference to claim 4, the i.v. bag would be at least one flexible membrane wall moveable to pump medical fluid.

In reference to claim 6, though a portable dialysis fluid flow path is not specifically disclosed, since the bag is disclosed to be an i.v. bag the use of such a bag to hold dialysis fluid would be well known to one of ordinary skill in the art and therefore utilizing

such a bag as a receptacle as claimed would be an obvious variant in view of the Cohen.

In reference to claims 9 and 10, the circuit measures the capacitance in methods well known in the art, according the disclosure of Cohen, and therefore would meet the limitations of these claims. For support in the disclosure, please see column 5 lines 3-15).

In reference to claim 11, the capacitor plates are shown to be substantially parallel in various figures.

In reference to claim 13, though the device is not specifically disclosed to be used with continuous flow peritoneal dialysis, it is the opinion of the examiner that such a usage is well within the preview of one of ordinary skill in the art as dialysis can be performed using a plastic i.v. type bag and therefore such a system would be an obvious variant for one of ordinary skill in the art at the time of the invention. With this in mind, the limitations of claim 13 are in the same scope as those of claims 1 and 12 and therefore the examiner feels that the limitations of claim 13 have been discussed with regard to the discussion of claims 1 and 12.

In reference to claims 18 and 19, these limitations were discussed at length above with regard to the discussion of claims 2 and 3 and the disclosure of Cohen.

In reference to claims 21 through 27, though these claims are not specifically disclosed in the Cohen reference, the limitations expressed are inherent to a device for administering medication to a patient. Since such a device is already well known to one of ordinary skill in the art, and the Cohen reference states that it can be used with any

container, whereby the container is related in the context of a device for providing a medication to a patient, such as a pump chamber. Therefore, it is the opinion of the examiner that since the medication distribution device is not what the applicant is claiming as his invention, and that such a device is well known, then the limitations with regard to such a device would also be well known to one of ordinary skill in the art at the time of the invention.

In reference to claim 35, utilizing a fixed time interval is not explicitly disclosed, but the use of a fixed time interval would be obvious to one of ordinary skill in the art. For example, a fixed time interval would be used when you may be comparing to previous results for calibration.

In reference to claims 37-39, 42, 46, 48-50, and 51-73 these method and apparatus limitations claimed are all viewed as obvious to one of ordinary skill in the art since the claims are a mere rehashing of claims presented earlier in the application and are similar in scope, concept, and/or method practiced as claims previously covered in detail earlier in this action.

8. Claims 6-10, 29, 41, 48-50, 57-59, 60-66, and 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al..

In reference to claim 6, though a portable dialysis fluid flow path is not specifically disclosed, since the bag is disclosed to be an i.v. bag the use of such a bag to hold dialysis fluid would be well known to one of ordinary skill in the art and therefore utilizing such a bag as a receptacle as claimed would be an obvious variant in view of the Brown.

In reference to claims 7 and 8, in column 5 beginning with line 5 through line 11, Brown discloses various embodiments of the capacitors whereby the capacitor plates can take on various shapes, one of which would be the actual shape of the container. Therefore a plate with a non-planar shape and a plate which is substantially the same shape as the container either full or empty (since the drip chamber never changes shape) are disclosed (also see column 5 lines 17-18 whereby a curved plate is specifically disclosed).

In reference to claims 9 and 10, the circuit measures the capacitance in methods well known in the art, according the disclosure of Brown, and therefore would meet the limitations of these claims. For support in the disclosure, please see column 5 lines 33 – column 9 line 63).

In reference to claim 29, a processor to determine a total volume from a plurality of volumes is not specifically disclosed, the use of a processor and its various functions would be obvious to one of ordinary skill in the art and would be deemed as an obvious variant of the design chosen by Brown.

Claim 41 is similar to claim 7, which is discussed in detail 3 paragraphs above.

Claims 48-50 are intended use claims being as a i.v. bag can be used for various types of dialysis, and therefore these limitations are deemed in the general spirit of the invention disclosed by Brown.

Claims 57-73 are also deemed to be various methods and/or apparatus claims that are in the same scope as claims, which are previously covered in claim discussions

above and are therefore deemed as obvious to one of ordinary skill in the art in view of the disclosure of Brown.

Response to Arguments

Applicant's arguments with respect to claims 1-73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney T. Frank whose telephone number is (571) 272-2193. The examiner can normally be reached on M-F 9-5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTF
March 20, 2005

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800